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Emboldened Government Pursuit and Prosecution of Healthcare Fraud and Abuse

In recent years, the Department of Justice ("DOJ") and the Office of the Inspector General ("OIG") have demonstrated an increased willingness to use the tools which Congress has provided them in order to combat healthcare fraud and abuse. Primarily, these tools consist of: (1) the Anti-Kickback Statute ("AKS"); (2) the Stark Law ("Stark"); and, (3) the False Claims Act ("FCA"). The AKS makes it a felony for any person to knowingly and willfully solicit, offer, receive, or pay any remuneration in exchange for the referral of a patient for healthcare services paid by a federal healthcare program.[1] On the other hand, Stark prohibits physicians or immediate family members of physicians from referring Medicare or Medicaid patients to an entity for a designated health service, if the physician or a family member has a financial relationship with that entity.[2] Finally, the FCA creates civil liability for any person who knowingly presents a false or fraudulent claim for payment to an officer or employee of the United States for payment or approval.[3] Using the FCA in conjunction with either of the other laws, particularly Stark, presents a formidable tool for the government in policing healthcare fraud and abuse, especially because the FCA contains a *whistleblower* provision.[4] This *whistleblower* provision allows any private citizen to enforce the FCA by filing a *qui tam* action against an entity on behalf of the government. The government may then intervene, and assume primary responsibility for prosecuting the lawsuit, and the *whistleblower*, the private citizen who instigated the proceedings, may recover a portion of any damages that the government recovers.[5]

Since 1998, the government agencies responsible for prosecuting healthcare fraud and abuse, the DOJ and OIG, have demonstrated an increased willingness to pursue claims under the AKS, Stark, and FCA, as well as to prosecute increasingly complicated sets of violations. Part one of this three part series introduces the statutory and regulatory framework of relevant statutes, the teams responsible for investigating healthcare fraud and abuse, and relevant theoretical concepts involved in healthcare fraud and abuse lawsuits. Part two of this series, scheduled to be released in the monthly January 2014 issue of Health Capital Topics, will discuss certain notable violations of the above-mentioned statutes. Part three of this series, scheduled to be released in the monthly February 2014 issue of Health Capital Topics, will explore how the DOJ and OIG are prosecuting increasingly complex lawsuits and dramatically influencing the level of payment utilized in establishing *Fair Market Value* ("*FMV*") and *Commercial Reasonableness* ("*CR*").

Recently, a variety of investigatory programs and teams have been established to assist the DOJ and OIG in identifying and pursuing healthcare fraud and abuse claims. In 2005, the *Recovery Audit Contractors* ("*RAC*") program was established, and was tasked with identifying improper Medicare overpayments and underpayments by monitoring: (1) payments for medically unnecessary services; (2) payments for incorrectly coded services; and, (3) payments for services not supported by sufficient documentation.[6] During its three-year demonstration period, the *RAC* Program recovered $1.03 billion in improper Medicare payments, and, subsequently, Congress required that the *RAC* program be permanently established in all 50 states by January 1, 2010.[7] In 2008, the Centers for Medicare & Medicaid Services ("CMS") awarded contracts to four commercial *RAC* auditing firms, each responsible for a specified region of the United States.[8] In addition to the *RAC* program, CMS created the *Comprehensive Error Rate Testing* ("*CERT*") program in order to determine improper Medicare *fee-for-service* payments.[9] CMS utilizes *CERT*'s results to provide Congress with an estimate of the annual amount of improper Medicare payments made to providers throughout the year.

On May 20, 2009, President Barack Obama signed the *Fraud Enforcement and Recovery Act* ("*FERA*"), which reduced the government's burden of proof in FCA cases by no longer requiring the government to show a person's *specific intent* to defraud in determining liability.[10] Also in May of 2009, the Department of Health and Human Services ("HHS") and DOJ established the *Healthcare Fraud Prevention and Enforcement Action Team* ("*HEAT*") with funds from President Obama's budget.[11] *HEAT* focuses on investigating and identifying patterns of potentially fraudulent activity.[12] Since it its January 2009 inception, HEAT has recovered over $6.6 billion for the federal government under the FCA.[13] Finally, the *Medicare Fraud Strike Force*, another HHS-DOJ collaboration founded in 2007, performs investigatory functions

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similar to *HEAT*. As a result of *HEAT* and *Medicare Fraud Strike Force* collaboration, the *Medicare Fraud Strike Force* identified and investigated one of the largest healthcare fraud recoveries to date, eventually charging 107 medical professionals for fraudulently billing Medicare over $452 billion.[14]

Once healthcare fraud has been identified, the OIG and DOJ must prosecute the claim. As mentioned above, the AKS makes it a felony for any person to knowingly and willfully solicit, offer, receive, or pay any remuneration in exchange for the referral of a patient for healthcare services paid by a federal healthcare program.[15] There are, however, a number of "*safe harbors*" to the definition of remuneration.[16] Strict compliance with a *safe harbor* will preempt the OIG and DOJ from pursuing a claim based on an AKS violation; however, in instances where an entity does not strictly comply with a *safe harbor*, the OIG has stated that it will evaluate the facts and circumstances specific to every agreement in order to determine violation of the AKS.[17] Specifically, the OIG has assessed: (1) whether compensation for the services provided was at fair market value; (2) whether the compensation paid varied with the number of patients treated; (3) whether or not parties intended compensation to be offered for referrals; (4) the specificity of quality component measures within the agreement; and, (5) whether or not the agreement was for a limited duration.[18]

The majority of recent claims have involved *qui tam whistleblowers* alleging that entities have violated the FCA through violating Stark's prohibition of physician self-referral. As mentioned above, Stark prohibits physicians or immediate family members of physicians from referring Medicare or Medicaid patients to an entity, e.g., a hospital, for a designated health service ("DHS") if the physician or a family member of the physician has a financial relationship with that entity.[19] The Centers for Medicare & Medicaid Services ("CMS") promulgated a list of 10 types of DHS, the most notable of which, for the purposes of this series, are "*inpatient and outpatient hospital services,*"[20] because the majority of cases arising under Stark result from hospitals billing for inpatient and/or outpatient hospital services. Financial relationships are defined as any ownership, investment, or compensation agreement with an entity, unless otherwise covered by an exception.[21] There are also 27 separate Stark exceptions.[22] Therefore, in lawsuits alleging violations of Stark, the government must prove each element of a Stark violation: (1) a financial relationship between the physician and entity; (2) a referral for a designated health service by the physician to the entity; and, (3) submission of the claim associated with the referral by the entity to Medicare or Medicaid for the designated health service.[23] If and when the government demonstrates proof of each element of a Stark violation, the burden shifts to the defendant to establish that its financial relationship or conduct was protected by a Stark exception.[24]

Much of the argument in a Stark lawsuit centers on whether or not an entity's relationship with a physician fulfills the requirements of a Stark exception. The majority of these Stark exceptions require that any reimbursement paid by the entity to the physician be consistent with *FMV* and *commercially reasonable*,[25] and, therefore, much of the argument centers on whether compensation provided to physicians was consistent with *FMV*.

In addition to Stark violations, payment in excess of *FMV* for the purchase of physician practices also violates the AKS prohibition against payment for referrals.[26] Congress and various government agencies have promulgated definitions of *FMV* and *CR*, the most relevant of which are:

> "*…fair market value in arms-length transactions…not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.*"[27]

> "*Fair market value means the value in arm's-length transactions, consistent with the general market value. General market value means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.*"[28]

> "*We believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace… we intend to accept any method [for establishing FMV] that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location*

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at issue, by parties in arm's-length transactions who are not in a position to refer to one another…the amount of documentation that will be sufficient to confirm FMV…will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations."[29]

Once it is determined that Stark, or the AKS, was violated, the government continues with its FCA analysis. Specifically, the FCA requires that: (1) a false or fraudulent claim (2) was presented by the defendant to the United States for payment or approval (3) with knowledge that the claim was false.[30] Any claim that (1) violates Stark or the AKS and (2) is presented to a government program for payment is also false and/or fraudulent because entities submitting claims for payment under Medicare or Medicaid must certify compliance with any applicable laws as a pre-condition to receiving payment.[31] Therefore, in addition to Stark violations the government need only prove that an entity knowingly violated Stark in order to recover under the FCA.[32]

The majority of fraud and abuse cases analyzed within the subsequent parts of this series follow the aforementioned statutory and regulatory framework, with a particular focus on Stark violations, exceptions, and a *FMV* and *CR* analysis.

1 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)

2 "Limitations on certain physician referrals" 42 U.S.C. § 1395nn(a)

3 "False Claims Act" 31 U.S.C. § 3729(a)

4 *Ibid*, 31 U.S.C. § 3730(b)

5 *Ibid*, 31 U.S.C. §§ 3730(c)(1), § 3730(d)(1)

6 "Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services: FY 2010 Report to Congress" Centers for Medicare and Medicaid Services, 2011, p. 2

7 "CMS Announces New Recovery Audit Contractors to Help Identify Improper Medicare Payments" Centers for Medicare and Medicaid Services, October 6, 2008, https://www.cms.gov/...a=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date (Accessed September 12, 2011); "Recovery Audit Contractors' Fraud Referral" Office of Inspector General, February 2010, p. i; "Recovery Audit Contractor (RAC) Program" American Hospital Association, 2011, http://www.aha.org/advocacy-issues/rac/index.shtml (Accessed 9/12/11)

8 "Recovery Audit Program: Overview" Centers for Medicare and Medicaid Services, September 6, 2011, http://www.cms.gov/recovery-audit-program/ (Accessed 9/12/11); "RAC National Program and Contractor Information" American Hospital Association, 2011, http://www.aha.org/advocacy-issues/rac/contractors.shtml (Accessed 9/12/11)

9 "Comprehensive Error Rate Testing (CERT)" Centers for Medicare and Medicaid Services, May 15, 2012, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/index.html?redirect=/CERT/ (5/23/12)

10 "Fraud Enforcement and Recovery Act, Sec. 4" Pub. Law 111-21, 123 Stat. 1617 (May 20, 2009), p. 1622

11 "Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention & Enforcement Action Team" U.S. Department of Justice, Press Release (May 20, 2009), http://www.hhs.gov/news/press/2009pres/05/20090520a.html (Accessed 9/12/12)

12 "Sebelius: New Fraud Prevention Team Will Turn Up Heat," By Ben Amirault, HealthLeaders Media, May 21, 2009, http://www.healthleadersmedia.com/content/233446/topic/WS_HLM2_FIN/Sebelius-New-Fraud-Prevention-Team-will-Turn-up-Heat.html (Accessed 5/21/09)

13 "Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly $4.1 Billion: Largest Sum Ever Recovered in Single Year" U.S. Department of Health and Human Services, News Release (April 14, 2012), http://www.hhs.gov/news/press/2012pres/02/20120214a.html (Accessed 9/9/12)

14 "New Tools to Fight Fraud, Strengthen Federal and Private Health Programs, and Protect Consumer and Taxpayer Dollars" U.S. Department of Health and Human Services, Fact Sheet (July 26, 2012), http://www.healthcare.gov/news/factsheets/2011/03/fraud03152011a.html (Accessed 9/12/12)

15 *Ibid*, 42 U.S.C. § 1320a-7b(b)

16 "Exceptions" 42 C.F.R. § 1001.952

17 Department of Health and Human Services, Office of the Inspector General, Advisory Opinion No. 12-22 (December 31, 2012), pp.12-13

18 *Ibid*

19 *Ibid*, 42 U.S.C. § 1395nn(a)

20 *Ibid*, 42 U.S.C. § 1395nn(h)(6)

21 "Definitions" 42 C.F.R. § 411.351

22 *Ibid*, 42 U.S.C. § 1395nn(b)-(e); "General exceptions to the referral prohibition related to both ownership/investment and compensation" 42 C.F.R. § 411.355(a)-(i); "Exceptions to the referral prohibition related to ownership or investment interests" 42 C.F.R. § 411.356(a)-(c); "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357(a)-(p)

23 "USA ex rel. Elin Baklid-Kunz v. Halifax Hospital Medical Center", Order, No. 6:09-cv-01002-GAP-TBS (M.D. Fla. Nov. 11, 2013), ECF No. 396, p. 10

24 *Ibid*

25 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which they have Financial Relationships" Federal Register Vol. 66, No. 3, (January 4, 2001), p. 944; *Ibid*, 42 U.S.C. § 1395nn(b)-(e); *Ibid*, 42 C.F.R. § 411.355(a)-(i); *Ibid*, 42 C.F.R. § 411.356(a)-(c); *Ibid*, 42 C.F.R. § 411.357(a)-(p)

26 "Am. Lithotripsy Soc'y v. Thompson," 215 F.Supp.2d 23, 27 (D.D.C. 2002); "OIG Letter to IRS", by D. McCarty Thornton, Office of the Inspector General, December 22, 1992, http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm (Accessed 12/10/13)

27 "Program Integrity; Medicare and State Health Care Programs; Permissive Exclusions" 42 C.F.R. § 1001.952(b)(5)

28 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which they Have Financial Relationships (Phase III): Final Rule" Federal Register Vol. 72, No. 171 (September 5, 2007), p. 51081

29 *Ibid*, Federal Register Vol. 66, No. 3, (January 4, 2001), p. 916

30 *Ibid*, No. 6:09-cv-01002-GAP-TBS (M.D. Fla. Nov. 11, 2013), ECF No. 396, p. 11

31 "United States ex rel. Thompson v. Columbia/HCA Healthcare Co.," 20 F. Supp.2d 1017, 1041 (S.D. Tex. 1998)

32 *Ibid*, No. 6:09-cv-01002-GAP-TBS (M.D. Fla. Nov. 11, 2013), ECF No. 396, p. 12.

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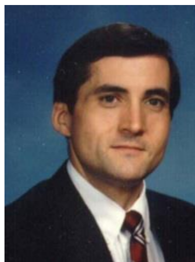

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